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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/627,896	07/27/2000	Man Sung Co	GNN-5315DVI	2462

7590

09/23/2003

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EXAMINER

GAMBEL, PHILLIP

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 09/23/2003

27

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. <u>09/627896</u>		Applicant(s) <u>CO</u>	
	Examiner <u>GAMBEL</u>		Art Unit <u>1644</u>	

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 6/16/03

2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) 5 is/are withdrawn from consideration.

5) ☐ Claim(s) 1-4, 6-26 is/are allowed.

6) ☒ Claim(s) 1-4, 6-26 is/are rejected.

7) ☐ Claim(s) 1-4, 6-26 is/are objected to.

8) ☐ Claim(s) 1-4, 6-26 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on 1-4, 6-26 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on 1-4, 6-26 is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. .

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☒ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u> </u>
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u> </u>	6) <input type="checkbox"/> Other: <u> </u>

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 6/26/03 (Paper No.25), has been entered.

Applicant's amendment, filed 6/26/03 (Paper No. 26), has been entered.

Claims 1-3, 6, 10-12, 16-17 and 22-23 have been amended.

Claims 1-4 and 6-26 are being acted upon as they read on the elected invention.

Claim 5 has been withdrawn from consideration by the examiner 37 CFR 1.142(b), as being drawn to nonelected invention

2. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-4 and 6-26 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. The specification as originally filed does not provide support for the invention as now claimed:

"at least a portion of an immunoglobulin of human origin derived from the III2R (SEQ ID NOS: 25,29) and/or H2F (SEQ ID NOS: 26,30 variable region"

Applicant's amendment, filed 6/26/03 (Paper No. 26), does not provide sufficient direction for the written description for the above-mentioned "limitations".

Pages 21-22 of the instant specification disclose that the framework of the light chain variable regions are from the H2F human antibody and the framework for the heavy chain of variable region are from the III2R (note the specification still discloses I2R) human antibodies, respectively.

Therefore, the newly amended claims appear to broaden the original disclosure to the use of III2R and H2F for both heavy and light chain, whereas the specification as filed appears to limit the framework of the light chain variable regions are from the H2F human antibody and the framework for the heavy chain of variable region are from the III2R (note the specification still discloses I2R) human antibodies, respectively.

Furthermore, the specification as filed does not appear to support the "at least a portion" limitation as well.

The specification does not provide blazemarks nor direction for the instant methods encompassing the above-mentioned "limitations" as currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office action

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above. See MPEP 714.02 and 2163.06

4. Applicant's amendment, filed 6/26/03 (Paper No. 26) has obviated the previous objection to the amendment, filed 10/11/02 (Paper No. 17), under 35 U.S.C. 132, new matter.

5. Applicant's amendment and Sequence submission, filed 6/26/03 (Paper No. 26), has obviated the previous rejections under 35 U.S.C. 112, first and second paragraphs, with respect to the "3D1" and "H2F", "I2R" antibodies.

6. Upon reconsideration of applicant's arguments, filed 6/26/03 (Paper No. 26), the previous rejection under 35 U.S.C. § 103(a) as being unpatentable over Freeman et al.. (U.S. Patent No. 6,130,316) in view of art known gene cloning and expression strategies for deriving recombinant antibodies and fragments thereof, as disclosed/admitted on pages 10-28 or Examples I (only indicated as Exemplification on page 34 of the specification) Examples II/III of the instant specification or as cited by references on the 1449, as evidenced by Queen et al. (U.S. Patent No. 5,585,089)(1449; #AB) and as evidenced by Harlow and Lane (Eds., Antibodies: A Laboratory Manual, Cold Spring Harbor Laboratory 1988, Chapter 3, pages 23-35) has been withdrawn.

B7-2 specific antibodies comprising III2R and H2F framework modifications appear free of the prior art.

7. No claim is allowed.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 872-9306.



Phillip Gambel, Ph.D.
Primary Examiner
Technology Center 1600
September 22, 2003